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(54) Title: APPARATUSES AND METHODS FOR DISSECTION

(57) Abstract

A dissector for separating tissue within a patient's abdomen is provided. The dissector can be provided in the form of an inflatable generally heart-shaped balloon having proximal and distal ends. Attached adjacent the distal end are first and second projections for dissecting selected tissues, while the proximal end is provided with an opening for receiving a tube for inflating the balloon. A slot is defined by, and disposed between, the first and second projections.

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APPARATUSES AND METHODS FOR DISSECTION

TECHNICAL FIELD OF THE INVENTION

The present invention relates generally to apparatuses and methods for dissecting tissues and/or creating an anatomical space within a patient, and, more particularly, to apparatuses and methods for dissecting tissues and/or creating an anatomical space within the space of Retzius while avoiding contact with selected neural and vascular structures therein.

BACKGROUND OF THE INVENTION

Female stress urinary incontinence (SUI), which is defined as the unintentional loss of urine, can be a socially unacceptable problem for many women. Referring to Fig. 1 for discussion purposes, female SUI can be caused by the loss of muscular support or pressure about the urethra 20 at the urethravesicular junction (UVJ) 22 (i.e., the region where the urethra enters the bladder). Prior to childbirth, a female's periurethral fascia 24 is generally attached to the pubic bone 26, thereby supporting the urethra at the proper angle. Following childbirth, the periurethral fascia 24 can separate from the pubic bone such that the urethra 20 will sag into the vagina, as generally shown in Fig. 1. When this situation occurs, the pressure which can be exerted on the urethra to maintain continence is diminished. During coughing, sneezing, or similar events, pressure is exerted on the dome of a filled bladder. However in women suffering from SUI, the urinary fluid pressure increase which accompanies these events is not balanced by a corresponding increase in the pressure exerted on the urethra. This pressure imbalance can lead to an uncontrolled loss of urine.

Urethropexy is a surgical procedure wherein the periurethral fascia 24 is suspended adjacent the pubic bone 26 so that it approximates its original high retropubic position. In one form of this procedure, the periurethral fascia 24 is suspended from the periosteum of the pubic bone by sutures and repositioned so that the urethra 20 is returned to the desired angle. This procedure was first developed by Drs. Marshall, Marcheti, and Krantz, and is known as the "MMK" procedure. While the MMK

procedure has been modified over the years, the essential principles have remained unchanged. In 1955 Burch developed the technique of affixing the periurethral fascia bilaterally to Cooper's ligament, thereby resulting in a technically easier procedure because of the previous difficulties in passing a needle through the periosteum of the pubic bone. Although the Burch procedure has been performed laparoscopically, the five-year failure rate for the open Burch procedure is approximately 60%. A laparoscopic Burch procedure is even more problematic since it is extremely difficult and time-consuming to tie sutures laparoscopically, and a similar failure rate is expected.

Alternatively, urological procedures such as that of Stamey, Raz and Peyerra have been developed, however these are typically blind procedures which require the passing of long needles through the rectus fascia to the periurethral fascia utilizing a cystoscope. Although these urological procedures avoid the 10-centimeter midline or Pfannenstiel incision and its required three-day or longer hospital stay, the gynecological procedures of MMK, Burch and others have proven to be the most effective. In addition to returning the UVJ to a high retropubic angle, these procedures result in the partial reattachment of the periurethral fascia to the pubic bone further enhancing restoration of continence to women who suffer from SUI. This reattachment is effected by dissection of most of the tissue from the pubic bone region prior to the suspension of the periurethral fascia so that scar tissue will post-operatively form between the suspended periurethral fascia and the pubic bone, thereby reattaching the periurethral fascia to the pubic bone.

Recently, a modified version of the MMK procedure has been developed which involves securing small anchors in the pubic bone on either side of the pubic symphysis. Each of the bone anchors has a suture attached thereto, and these sutures are threaded through the periurethral tissue on either side of the urethra. The sutures are then tied off in the abdomen so that the periurethral tissue is pulled upward, which in turn restores the angle of the urethra at the UVJ, thereby restoring the urethra to its proper location. While this MMK procedure is highly effective, it is a lengthy and complicated procedure which can generally only be performed by highly-skilled surgeons. Another modified version of the MMK procedure is described in my copending application S/N 08/719,484, which is incorporated herein by reference. In this preferred laparoscopic procedure, an anchor insertion tool is passed through the operative channel of the laparoscope (or other cannula) into the patient's body, and an anchor is secured to the

pubic bone of the patient's body on either side of the urethra. Each anchor has a suture extending therefrom which is retrieved by a suture retrieval tool which is positioned within the vagina by a surgical template. The suture retrieval tool is passed through the vaginal mucosa and into the space of Retzius so that the sutures can be snared and pulled into the vagina by the suture retrieval tool. The sutures are then tied so that the periurethral fascia is returned to its original high retropubic position.

In the traditional open urethropexies of MMK and Burch, the surgeon bluntly dissects the space of Retzius by blindly sweeping his or her fingers from left to right and right to left in order to detach the periurethral fascia and areolar adventitial tissue from the pubic bone. However, this procedure typically results in substantial operative and post-operative bleeding which requires drainage of the space of Retzius. The increased bleeding is caused by lateral dissection into the obturator blood vessels as well as traumatic injury to blood vessels supplying the dorsal urethra, the latter blood vessels being disposed within the dorsal urethral neurovascular plexes. These complications have been furthered by the fact that the location and composition of the dorsal urethral neurovascular plexes was unknown until its discovery by the Applicant.

Another common post-operative complication with urethropexy is the onset of intrinsic sphincter deficiency (ISD). The urethra, at a point proximal to the bladder, has a circumferential sphincter muscle with a resting state that is sufficient to close the urethra. ISD is a condition wherein the sphincter muscle is in a resting open state rather than a resting closed state. Disruption of the blood supply to the urethra, which is provided by vascular structures located in the dorsal urethral neurovascular plexes, can result in sphincter muscle devascularization and failure thereby causing ISD. Similarly, traumatic damage to the motor and sensory nerves supplying the urethra, which are also disposed within the dorsal urethral neurovascular plexes, can similarly result in the sphincter muscle adopting a resting open state resulting in ISD. Thus, Applicant has determined that contact with the dorsal urethral neurovascular plexes during a urethropexy can cause post-operative complications involving both bleeding as well as ISD.

The present invention offers a unique dissector for separating tissues in the space of Retzius while avoiding contact with selected anatomical structures, including as the dorsal urethral neurovascular plexes. While these apparatuses and methods of

employing the same are particularly suited for laparoscopic urethropexy, they are not so limited.

SUMMARY OF THE INVENTION

A dissector for dissecting the space of Retzius in a patient is provided. The dissector comprises a body having proximal and distal ends with a longitudinal axis extending therebetween. A pair of projections extend away from the distal end of the body with one of the projections being disposed on each side of said longitudinal axis. The projections have a base adjacent the distal end and a tip opposite the base such that the projections define a slot therebetween. Preferably, the length of the slot is less than the distance from the proximal end of the body to the bottom of the slot, and width of said slot is substantially constant in a direction from the base to the tip. This configuration advantageously provides a dissector of the present invention which preferably avoids dissection of the dorsal urethral neurovascular plexes while at the same time dissecting tissue within the space of Retzius to provide an anatomical working space therein.

The distal end of the body is provided with a rounded face adjacent the slot. The rounded face generally conforms to the shape of the dorsal urethral neurovascular plexes while the shape of the top surface of the projections generally conforms to the shape of undercarriage of the body of pubis. In a preferred form, a dissector of the present in invention is provided as an inflatable balloon, wherein the projections are preferably less than about 4 cm and/or greater than about 2 cm in length when the balloon is fully inflated. Preferably, the width of the slot is between about 2 and about 4 cm when the balloon is deflated, and about 2.5 cm when said balloon is fully inflated. At least one of the projections has a quarter projection width of at least about 1.5 cm and a half projection width of at least about 2 cm when said balloon is deflated. The maximum width of the body is preferably between about 10 and about 14 cm when the balloon is deflated, and the maximum height of the balloon is between about 5 and about 7 cm when the balloon is fully inflated.

A dissector of the present invention can be used for dissecting the space of Retzius in a patient by first inserting the dissector therein. The projections simultaneously dissect selected tissues within the space of Retzius adjacent the pubic

bone while the dorsal urethral neurovascular plexes is positioned within the slot so that dissection of the plexes is avoided. In addition, the body of the dissector dissects tissue to lateral points on either side of the urethra, the lateral points being between the urethra and the obturator blood vessels. More preferably, the lateral points are disposed at least about 1 cm from the obturator blood vessels. This latter dissection provides an anatomical space for the surgical procedures required by a laparoscopic or "mini-laparotomy" urethropexy or similar operation.

BRIEF DESCRIPTION OF THE DRAWINGS

While the specification concludes with claims particularly pointing out and distinctly claiming the invention, it is believed the same will be better understood from the following description taken in conjunction with the accompanying drawings in which:

Fig. 1 is a cross sectional view taken through the midline of a patient who has lost support of the periurethral tissue at the UVJ, and is thereby suffering from stress urinary incontinence;

Fig. 2 is a perspective view of the space of Retzius;

Fig. 3 is a perspective view of a fully inflated balloon made in accordance with the present invention;

Fig. 4 is a top view of the balloon of Fig. 3 when deflated and having phantom lines indicating the balloon's dimensions when fully inflated;

Fig. 5 is a cross-sectional side view of the balloon of Fig. 3, taken along line 5-5 thereof;

Fig. 6 is an exploded view of the balloon of Fig. 3 taken about circle 6 thereof, wherein the phantom lines have been removed for clarity;

Fig. 7 is an end view of the balloon of the present invention inserted into the space of Retzius, wherein certain tissues have been removed for clarity;

Fig. 8 is a perspective view of an alternate embodiment of a dissector of the present invention;

Fig. 9 is a partial cross-sectional side view of the pubic bone and balloon of Fig. 7 taken along line 9-9 thereof, wherein selected tissues have been removed to expose the pubic bone and the rectus muscle has been added for discussion; and

Fig. 10 is a partial bottom view of the pubic bone and the balloon of Fig. 7 taken along line 10-10 thereof, wherein selected tissues have been removed to expose the pubic bone.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring now to the drawings in detail wherein like numerals indicate the same elements throughout the views, Fig. 2 is a perspective view of the retropubic space or the space of Retzius 30 within a female patient. The space of Retzius is, in actuality, a "potential" space in that it contains various connective tissues or fats, known as the areolar adventitial tissue, as well as a more dense tissue commonly known as the periurethral fascia. Access to the anatomical structures of the space of Retzius often requires dissection and separation of these tissues. As used herein, the word "dissection" and its derivatives is intended to focus on the process of separating tissues along a plane by the application of a force to the tissues. Substantial dissection or separation of a selected tissue plane can be used to form an anatomical space within the space of Retzius, as discussed more fully hereafter.

For reference and as shown in Fig. 2, the space of Retzius 30 is bounded by the pubic symphysis 32 through which a medial or midline M extends. The inferior boundary of the space of Retzius consists, in part, of the periurethral fascia, which for discussion herein, can be more particularly described as right lateral periurethral fascia 34, left lateral periurethral fascia 36, and a medial periurethral fascia 38 which extends adjacent the urethra 20. Urethra 20 terminates at the bladder 23. Adjacent to the right and left periurethral fascia 34 and 36 and forming the anterolateral boundary of the space of Retzius are the obturator canals 40 through which the obturator blood vessels 42 pass. The dorsal urethral neurovascular plexes 44 is disposed adjacent the pubic symphysis 32.

In order to accomplish a urethropexy or other procedure in this region, the space of Retzius 30 must be first exposed and the tissues therein dissected so that an anatomical space can be created. In my laparoscopic urethropexy procedure, for example, the anatomical space is needed for the visualization of pertinent structures as well as access to the pubic bone for anchor placement. In addition, the tissues in the pubic bone region must be dissected to facilitate reattachment of the periurethral fascia to the pubic bone by the formation of scar tissue, as discussed more fully hereafter. Traditionally in an

open urethropexy, a 10 centimeter midline or Pfannenstiel incision is made in the patient's abdomen to fully expose the space of Retzius. Alternatively, a smaller infraumbilical incision can be made so that the urethropexy can be performed laparoscopically, wherein a the space of Retzius is not fully exposed but rather a laparoscope and surgical tools are typically inserted through a cannula for viewing and operating within the space of Retzius. A "mini laparotomy" urethropexy can also be performed wherein a pair of incisions, which are slightly larger than an infraumbilical incision for insertion of a laparoscope but less than the 10 centimeter midline or Pfannenstiel incision, is made so that the tips of surgical instruments can be inserted directly into the space of Retzius. In both the laparoscopic and mini-laparotomy urethopexies, it is critical that the space of Retzius be properly dissected.

The present invention is directed toward a dissector capable of dissecting or separating the tissues of the space of Retzius in a laparoscopic, mini-laparotomy, or similar urethropexy procedure while simultaneously avoiding various vascular and neural structures which, if damaged, can cause post-operative complications. More particularly, the dissector of the present invention is capable of not only dissecting the tissues of the space of Retzius so that an anatomical working space is created therein, but also of dissecting or separating selected tissues to facilitate reattachment of the periurethral fascia to the pubic bone while avoiding the dorsal urethral neurovascular plexes and obturator blood vessels. While the dissector of the present invention is particularly suited for use in a laparoscopic or "mini laparotomy" urethropexy, the present invention is equally suitable for use with other surgical procedures requiring selected separation of tissues within the space of Retzius.

Referring now to Fig. 3, a preferred dissector of the present invention is illustrated in the form of a generally heart-shaped, inflatable balloon 46 comprising a top face 48 and a bottom face 50. The faces define first and second projections 52 and 54 and a body 55 having a proximal end 56 and a distal end 58 and a longitudinal axis L extending therethrough. A slot 60 is defined by and disposed between projections 50 and 52. Top face 48 and a bottom face 50 are sealingly joined along seam 64 extending around the periphery of top and bottom faces 48 and 50. Seam 64 can be formed by heat sealing or adhesively bonding the top and bottom faces to each other at their periphery. Top and bottom faces 48 and 50 forming balloon 46 are preferably manufactured from

a flexible, substantially inelastic medical grade material which is suitable for use within a patient, such as polyvinyl chloride or PVC.

While it is preferred that balloon 46 is formed from a top and bottom face which are joined around their periphery as previously discussed, it is contemplated that other configurations can be equally suitable. For example, balloon 46 can be formed as a single, unitary structure, thereby eliminating the need for distinct top and bottom faces. Alternatively, balloon 46 can be formed from more than two faces which are joined at multiple seams. Further, while it is desirable that both top face 48 and bottom face 50 are formed from the same material, top face 48 and bottom face 50 can be formed from dissimilar materials. For instance, bottom face 50 can be formed from a material which is inelastic while the material forming top face 48 is elastic, the elastic top face thereby providing a preferential direction of inflation because it will expand outwardly to a greater extent at a given pressure than the inelastic bottom face. Still further, top face 48 and/or bottom face 50 can be provided with surface projections such as ridges, hemispheres, or the like, the projections being useful in dissecting or separating targeted tissue as the balloon expands.

As most clearly seen in Fig. 4 wherein the phantom lines represent balloon 46 in an inflated state, balloon 46 preferably has a maximum body width W when fully inflated which is less than the maximum body width W of balloon 46 in its deflated state. As used herein, the phrase "fully inflated" is intended to refer to an inflated state created by moderate hand pressure on a syringe or similar instrument inflating the balloon with a liquid, preferably saline solution. Body 55 preferably has a maximum body width W of between about 10 and about 14 cm when balloon 46 is deflated and a maximum body width W of between about 8 and about 12 cm when fully inflated, with the maximum body width W being disposed between proximal end 56 and distal end 58. As used herein, the phrase "body width" refers to the width of the body in a direction substantially perpendicular to the longitudinal axis L, as shown in Fig. 4. More preferably, the maximum body width W is about 12 cm when deflated and is about 10 cm when inflated, with the maximum body width W being disposed between about 3 and about 5 from slot line S in a direction toward proximal end 56 when balloon 46 is deflated and between about 2 and about 4 cm when inflated. Slot line S represents a line which is substantially tangent to the bottom or the lowermost point of slot 54 (i.e., the

point of slot 54 which is closest to proximal end 56 of body 55). Most preferably, the maximum body width W is disposed about 4 cm from slot line S when balloon 46 is deflated and about 3 cm when inflated.

The sides 66 of body 55 taper inwardly toward the longitudinal axis L in a direction proceeding from about the maximum width W toward the proximal end 56 and also taper inwardly from about the maximum body width W toward distal end 58. Both tapers are present when the balloon is deflated as well as fully inflated, as shown in Fig. 4. The former taper eases the removal of balloon 46 from a patient's abdominal cavity after an inflation/deflation cycle, as a blunt proximal end 56 is avoided which might interfere with removal, while the latter is a transition to the taper of the projections and also generally mirrors the shape of the path of the obturator blood vessels 42 as shown in Fig. 10.

Referring now to Fig. 5, opening 70 disposed at proximal end 56 is adapted to receive an inflation tube 72 or other device for inflating the balloon. Inflation tube 72 extends from a point within the interior 68 of the balloon 46, and may be attached to a pressurized fluid supply for inflating of balloon 46. Inflation tube 72 passes through opening 70 and sealingly engages body 48 thereat. The portion of inflation tube 72 disposed within balloon 46 preferably has a plurality of holes 74 so that a pressurized fluid passing through inflation tube 72 for inflating the balloon 46 can quickly fill the balloon, thereby outwardly expanding top face 48 and bottom face 50 so that balloon 46 forms a generally rounded inflated shape, as shown in Fig. 5. While it is preferred that the above-described arrangement is provided, other arrangements and structures are equally suitable for inflating balloon 46. For instance, opening 70 can be disposed at another location on balloon 46 or opening 70 can be provided with a mechanical fitting so that the inflation tube need not extend into the interior of balloon 46.

Balloon 46 is preferably sized overall to provide an internal volume of between about 300 and about 360 cc when fully inflated. A fully inflated balloon of the present invention having this volumetric capacity can advantageously create an anatomical space within the space of Retzius which is sufficient for laparoscopically viewing and performing surgical procedures within the abdomen, such as those required in a urethropexy. Although the interior of a balloon made in accordance with the present invention has been discussed as comprising a single cavity for simplicity and ease of

manufacture, interior 68 of a balloon of the present invention can also be compartmentalized or separated into several cavities or chambers with different inflation pressures being provided to each, thereby providing for preferential expansion of the balloon depending upon the relative pressures within the chambers. In one embodiment, a balloon can be divided into a top chamber and a bottom chamber wherein one of the chambers is provided with a higher pressure during use so that it has a relatively greater outward expansion than the other chamber.

As most clearly seen in Fig. 6, first projection 50 and second projection 52 preferably extend outwardly away from distal end 58. First and second projections 52 and 54 are disposed on either side of the longitudinal axis L and each has base 76 which is generally defined by the portion of slot line S between inner side 80 and outer side 82. Each projection also has a tip 78 which is disposed opposite base 76. Each of the foregoing structures is most clearly defined when balloon 46 is deflated. Each projection also has a projection length X which refers to the distance between base 76, as measured from slot line S, and tip 78. Preferably, the projections have a length X between about 1 and about 3 cm and, most preferably, about 2 cm when the balloon is deflated. When the balloon is inflated, the length X is between about 2 and about 4 cm, and, more preferably, about 3 cm.

Inner side 80 and outer side 82 of each projection taper inwardly toward each other when the balloon is deflated, with this inward taper being characterized by quarter projection width P_{25}, half projection width P_{50}, and three quarter projection width P_{75}. Quarter projection width P_{25}, half prosecution width P_{50}, and three quarter projection width P_{75} refer to the projection width at a point about 25%, about 50%, and about 75%, respectively, along the length X in a direction away from tip 78, as shown in Fig. 6. Preferably, quarter projection width P_{25}, half projection width P_{50}, and three quarter projection width P_{75} are between about 1.5 and about 3.5 cm, between about 2 and about 3 cm, and between about 2 and about 4 cm, respectively, when the balloon is deflated. More preferably, quarter projection width P_{25} is about 2 cm, half projection width P_{50} is about 2.5 cm, and three quarter projection width P_{75} is about 3 cm when deflated. When the balloon is fully inflated, the inner sides 80 are preferably substantially parallel to each other, as shown in Fig. 4. Tips 78 of the projections are preferably rounded or elliptical

in shape, such that the projections are free of any abrupt surface changes which might inadvertently damage tissue when inflated.

Slot 60 is preferably disposed between and defined by first and second projections 52 and 54. Slot 60 has a slot width which generally corresponds to a distance between inner sides 80 of the first and second projections 50 and 52, as seen in Fig. 6. As previously described, the inner sides of the projections which also define the shape of the slot 60 are substantially tapered outwardly away from the longitudinal axis L in a direction proceeding from base 76 to tip 78 so that the slot width is increasing in this direction when the balloon is deflated. The above-described shape of the slot can be characterized by quarter slot width S_{25}, half slot width S_{50}, and three quarter slot width S_{75}, where each width refers to the width at a point about 25%, about 50%, and about 75%, respectively, along the projection length X in a direction away from tip 78. When the balloon is deflated, the quarter slot width S_{25}, half slot width S_{50}, and three quarter slot width S_{75} are preferably between about 2 and about 4, and, more preferably, about 4, about 3.5 and about 2.5 cm, respectively. When the balloon is fully inflated, quarter slot width S_{25}, half slot width S_{50}, and three quarter slot width S_{75} are preferably substantially equal with the width being between about 2 and about 4 cm, and, more preferably, quarter slot width S_{25} , half slot width S_{50} and three quarter slot width S_{75} are about 2.5 cm. When balloon 46 is properly positioned within the space of Retzius, slot 60 preferably accommodates the dorsal urethral neurovascular plexes which is disposed therein while the first and second projections are located adjacent to and extend along either side of the plexes, as shown in Fig. 7. The above-described slot and projection arrangement advantageously provides a dissector of the present invention which can dissect or separate tissues in front of, and on either side of the dorsal urethral neurovascular plexes without disturbing this region.

As best seen in Fig. 6, the length or depth of slot 54 is the same as the projection length X, as both are measured as the distance from tip 78 to slot line S. Also as seen in Fig. 4, the depth of slot 54 is preferably less than the distance from proximal end 56 to the bottom of slot 54, the later distance preferably being about 17 cm when the balloon is deflated. This provides a dissector of the present invention which can accommodate the dorsal urethral neurovascular plexes (i.e., avoiding dissection of the same) while

dissecting tissues distal from the plexes adjacent the urethra to create an anatomical working space within the space of Retzius.

When balloon 46 is fully inflated, the body width W will decrease while the balloon increases in height H. As shown in Fig. 5, the balloon 46 preferably assumes a generally rounded shape when fully inflated having a maximum height H which is preferably disposed between distal end 58 and proximal end 56. As used herein, the phrase "height H" refers to the distance between top face 60 and bottom face 62. If balloon 46 is formed from materials which are substantially inelastic, the maximum height when balloon 46 is fully inflated is typically disposed at about the same location as the maximum width when it is deflated. The maximum height H is preferably between about 5 and about 7 cm, and, more preferably, about 6 cm, when balloon 46 is fully inflated. A balloon 46 of the present invention having a height H within these preferred ranges can create an anatomical space within the space of Retzius which provides sufficient room for laparoscopically performing the surgical procedures of a urethropexy, while minimizing bleeding caused by over-dissection.

When fully inflated, distal end 58 of balloon 46 preferably has a rounded face 92 which conforms to the shape of the dorsal neurovascular plexes and which is disposed adjacent slot 60. More particularly, rounded face 92 preferably has a face angle α of between about 30 and about 90 degrees. The phrase "face angle α", as used herein, refers to the angle between a line tangent to rounded face 84 at a point between about 1.5 and about 2.5 cm from slot line S, the line tangent to rounded face 84 being disposed within a plane passing through longitudinal axis L and which is generally perpendicular to a plane defined by longitudinal axis L and slot line S, as shown in Fig. 5. More preferably, face angle α is about 60 degrees at a point about 2 cm from slot line S.

First and second projections 52 and 54 preferably have a projection angle β when the balloon is fully inflated. The projection angle β refers to the angle between a line tangent to the projection at predetermined point from tip 78, as shown in Fig. 5. Preferably, the projection angle β is between about 30 and about 90 degrees at a point between about 2 and about 3 cm from tip 78, and more preferably, the projection angle β is about 40 degrees at a point about 2.5 cm from tip 78.

While the above-described balloon is the preferred form of a dissector of the present invention, it is contemplated that other embodiments are equally suitable for use

in a laparoscopic urethropexy or other similar surgical procedure. As shown in Fig. 8, a dissector of the present invention can be provided in the form of a substantially solid structure having the same dimensions and shape as the inflated balloon described above. In other words, a preferred solid dissector 120 of the present invention has a head 94 having first and second projections 152 and 154, a slot 160 defined by the projections, and an elongated handle 96 attached to head 94 opposite the projections and slot. Head 94 preferably has a length Z of at least about 2 cm from slot line S to back edge 98 of head 94, as shown in Fig. 7. The projections 152 and 154 have inner and outer sides 180 and 182 which taper inwardly toward each other. Because head 94 of solid dissector 120 has approximately the same shape and dimensions as the balloon previously described (when inflated), it can be inserted into the space of Retzius of a patient to dissect the same tissues while avoiding contact with the dorsal urethral neurovascular plexes. Dissector 120 can be formed from any medical grade material suitable for use in a patient. For example, dissector 120 can be formed by compression molding, injection molding, or the like using polyvinyl chloride or a similar forming material.

In a surgical operation, such as a urethropexy, a dissector of the present invention can be delivered into a patient's abdomen by various inserters known in the art. For example, the balloon dissector of the present invention can be secured to an elongate inserter which is inserted through the operative channel of a laparoscope (or similar cannula) into the patient's abdomen. Once inserted, the balloon is then inflated with a saline solution using a syringe or with a gas using a portable hand-held pump. Other inflation fluids may similarly be employed. The fluid source (e.g., a syringe or pump) is in fluid communication with the balloon, but is preferably located exterior of the patient for easy operation by the surgeon . The inserter can comprise a simple rod 99, such as that shown in Fig. 4, to which the balloon is releasably attached and rolled about so that the rod can propel the dissector through the cannula and into the patient's abdomen. Alternatively, the dissector can be retained about the rod by a sleeve, thereby dispensing with the need for directly attaching the dissector to the rod

More preferably, a balloon dissector of the present invention may be used in combination with one of the inserters described in U.S. Patent No. 5,540,711, which is incorporated herein by reference, by simply replacing the balloon described therein with that of the present invention. These inserters are manufactured by General Surgical

Innovations of Portola Valley, California, under the trademarks of SPACEMAKER I and SPACEMAKER II, and generally comprise a tunneling shaft having a bullet shaped tip to which the balloon of the present invention can be attached (as shown, for example, in Fig 3 of U.S. Patent No. 5,540,711). The tunneling shaft is slidably mounted within the bore of a trocar sleeve. The balloon dissector of the present invention can be provided with an attachment structure for engaging these tunneling shafts, (as described in U.S. Patent No. 5,540,711) this attachment structure comprising, for example, tubular sleeve 100. Tubular sleeve 100 can be disposed on top face 48 and can extend along a portion of, or the entire length of body 48, as best seen in Fig. 5. Tubular sleeve 100 can be provided with a weakened structural region (e.g., perforations in the sleeve) so that it can be easily separated from the tunneling shaft. While it is preferred to use one of the inserters described in U.S. Patent No. 5,540,711 for delivering a dissector of the present invention into the abdomen of a patient, it is contemplated that other inserters are equally suitable. For instance, U.S. Patent No. 5,370,134 to Chin et al. discloses an inserter having a balloon disposed at the distal end of a rigid shaft. The dissector of the present invention can replace the balloon of the Chin device for moving the dissector into a patient's abdomen.

In a most preferred laparoscopic urethropexy procedure using a balloon of the present invention in combination with a SPACEMAKER inserter, an infraumbilical incision is typically made in a patient's abdomen in order to provide access to the space of Retzius. A balloon of the present invention is attached to the tunneling shaft and inserted through the trocar sleeve. The tunneling shaft is then manipulated until the longitudinal axis L of the balloon is disposed adjacent the urethra within the space of Retzius (i.e., along the patient's midline). Specifically, the tunneling shaft is manipulated until the tip of the shaft reaches the pubic symphysis in the space of Retzius. Once positioned, the balloon is inflated by filling it with a saline solution which is delivered to the balloon under pressure from a syringe through an inflation tube so that the balloon will unroll laterally away from the inserter. The use of a saline solution for inflating the balloon is preferred as the weight of the saline solution within the balloon aids in downwardly dissecting the tissues within the space of Retzius. In addition, the amount of solution delivered to the balloon can be monitored for precise inflation of the balloon.

Inflation of the balloon will cause the body and the first and second projections of the balloon to expand outwardly away from the longitudinal axis L of the balloon. Preferably before inflation, the each projection is folded about its base rewardly toward the proximal end so that the tip is disposed between the base and the proximal end. This folding of the balloon tips can facilitate insertion of the balloon into the space of Retzius as a smaller more compact deflated structure is provided. After inflation, bases 76 are preferably disposed adjacent the proximal edge 84 of the pubic crest and tips 78 are disposed adjacent the distal edge 86 of the body of pubis, as shown in Fig. 9, while top face 48 of each projection conforms to the undercarriage 91 of the body of pubis. When positioned generally as described herein, inflation of the first and second projections simultaneously dissects or separates tissues on either side of the dorsal urethral neurovascular plexes such that damage to the dorsal urethral neurovascular plexes is avoided because the plexes are disposed within the slot of the balloon, as generally shown in Fig. 7. More preferably, the projections simultaneously dissect the tissue plane of the areolar adventitial tissue between the undercarriage of the body of pubis 90 and the medial periurethral fascia 38, thereby providing access to the undercarriage of the body of pubis 90 for the insertion of anchors as described in my U.S. Patent Application Serial No. 08/719,484. Dissection of this tissue also promotes post-operative reattachment of periurethral fascia, to that undercarriage of the body of pubis 90.

Inflation of the balloon also preferably dissects tissue adjacent the urethra distal from about the dorsal urethral neurovascular plexes and to lateral points on either side of the patient's midline, the lateral points being between the midline and the obturator blood vessels 42, as shown in Fig. 7. Particularly, the body of the balloon dissects the tissue plane of the areolar adventitial tissue between the bladder 23 and the undercarriage of the rectus muscle 102 beginning from about the point where the rectus muscle attaches to the proximal edge of the pubic crest 84 to lateral points which are disposed at least 1 cm from the obturator blood vessels 42. More preferably, this dissection also forms an anatomical space within the space of Retzius of sufficient size that the surgical procedures of the urethropexy can be performed laparoscopically once the balloon is removed.

The present invention also can prevent excessive bleeding because of the controlled lateral dissection in the space of Retzius, which, in particular, avoids contact

with the obturator blood vessels 42. Preferably, outer sides 82 generally conform to the shape of the superior edge 88 of the obturator foramen 87 so as to avoid the vascular structures (e.g., obturator blood vessels 42) exiting from the obturator canal 40, as shown in Fig. 10. The present invention advantageously prevents post-operative intrinsic sphincter deficiency because contact with the dorsal urethral neurovascular plexes is avoided, as previously described. Avoidance of the plexes prevents a disruption of the vascular blood supply to the urethra which can lead to urethral muscle devascularization and failure. Similarly, prevention of damage to the motor and sensory nerves of the dorsal urethral neurovascular plexes can insure continued muscle tone, the absence of which can also be a cause of intrinsic sphincter deficiency.

Having shown and described the preferred embodiments of the present invention, further adaptions of the dissector described herein can be accomplished by appropriate modification by one of ordinary skill in the art without departing from the scope of the present invention. Several of such potential modifications have been mentioned, and others will be apparent to those skilled in the art. The particular embodiments shown and described herein are intended only as preferred exemplary arrangements of the various structures and functions of the present invention. Accordingly, the scope of the present invention should be considered in terms of the following claims and is understood not be limited to the details of structure and operation shown and described in the specification and drawings.

What is claimed is:

1. A dissector for dissecting the space of Retzius in a patient, comprising:

a body having proximal and distal ends with a longitudinal axis extending therebetween;

a pair of projections extending away from said distal end of said body, one of said projections being disposed on each side of said longitudinal axis, said projections having a base adjacent said distal end and a tip opposite said base; and

said projections defining a slot.

2. The dissector of claim 1, wherein the length of said slot is less than the distance from said proximal end to the bottom of said slot.

3. The dissector of claim 1, wherein the width of said slot is substantially constant in a direction from said base to said tip.

4. The dissector of claim 1, wherein said distal end further comprises a rounded face adjacent said slot, said rounded face generally conforming to the shape of the dorsal urethral neurovascular plexes.

5. The dissector of claim 1, wherein the shape of the top surface of said projections generally conforms to the shape of undercarriage of the body of pubis.

6. The dissector of claim 1, wherein said dissector is an inflatable balloon.

7. The dissector of claim 6, wherein said balloon has a rounded face adjacent said slot, said rounded face having a face angle of at least about 30 degrees when said balloon is fully inflated.

8. The dissector of claim 6, wherein the top surface of said projections further comprise a projection angle when said balloon is fully inflated, said projection angle being at least about 30 degrees.

9. The dissector of claim 8, wherein said projection angle is between about 30 and about 90 degrees.

10. The dissector of claim 6, wherein said projections are less than about 4 cm in length when said balloon is fully inflated.

11. The dissector of claim 10, wherein said projections have a length greater than about 2 cm when said balloon is fully inflated.

12. The dissector of claim 6, wherein the width of said slot increases in a direction from said base to said tip when said balloon is deflated.

13. The dissector of claim 6, wherein the width of said slot is between about 2 and about 4 cm when said balloon is deflated.

14. The dissector of claim 6, wherein the width of said slot is about 2.5 cm when said balloon is fully inflated.

15. The dissector of claim 6, wherein one of said projections has a quarter projection width of at least about 1.5 cm when said balloon is deflated.

16. The dissector of claim 15, wherein one of said projections has a half projection width of at least about 2 cm when said balloon is deflated.

17. The dissector of claim 6, wherein said body has a maximum width of between about 10 and about 14 cm when said balloon is deflated.

18. The dissector of claim 6, wherein said balloon has an internal volume of between about 300 and about 360 cc.

19. The dissector of claim 6, wherein said body has a maximum height of between about 5 and about 7 cm when said balloon is fully inflated.

20. An apparatus for dissecting the space of Retzius in a patient, comprising:

(a) a dissector having:

(i) a body having proximal and distal ends with a longitudinal axis extending therebetween;

(ii) a pair of projections extending away from said distal end of said body, one of said projections being disposed on each side of said longitudinal axis;

(iii) said projections defining a slot, said slot being sized to receive the dorsal urethral neurovascular plexes such that dissection of said plexes is avoided; and

(b) an inserter for inserting said dissector into the space of Retzius.

21. The apparatus of claim 20, wherein the width of said slot increases in a direction from said base to said tip.

22. The apparatus of claim 20, wherein the length of said slot is less than the distance from said proximal end to the bottom of said slot.

23. The apparatus of claim 20, wherein said dissector is an inflatable balloon.

24. The apparatus of claim 23, wherein said projections are less than about 4 cm in length when said balloon is fully inflated.

25. The apparatus of claim 24, wherein said projections have a length of greater than about 2 cm when said balloon is fully inflated.

26. A method for dissecting the space of Retzius in a patient, comprising the steps of:

(a) providing a dissector, said dissector having:

(i) a body, said body having a proximal end, a distal end, and a longitudinal axis; and

(ii) a pair of projections extending from the distal end of said body on either side of said longitudinal axis, said projections defining a slot therebetween;

(b) inserting said dissector into said space of Retzius of the patient; and

(c) simultaneously dissecting tissue with each of said projections, wherein the dorsal urethral neurovascular plexes is positioned within said slot such that dissection of said plexes is avoided.

27. The method of claim 26, further comprising the step of dissecting tissue with said body to lateral points on either side of the urethra, said lateral points being between the urethra and the obturator blood vessels.

28. The method of claim 26, wherein said lateral points are disposed at least about 1 cm from the obturator blood vessels.

29. The method of claim 26, wherein said dissector is provided in the form of a balloon.

30. The method of claim 29, wherein said balloon has a rounded face adjacent said slot, said rounded face having a face angle when said balloon is fully inflated, said face angle being at least about 30 degrees.

31. The method of claim 29, wherein the upper face of said projections have a projection angle when said balloon is fully inflated, said projection angle being at least about 30 degrees.

32. The method of claim 29, wherein said projections have a length of less than about 4 cm when said balloon is fully inflated.

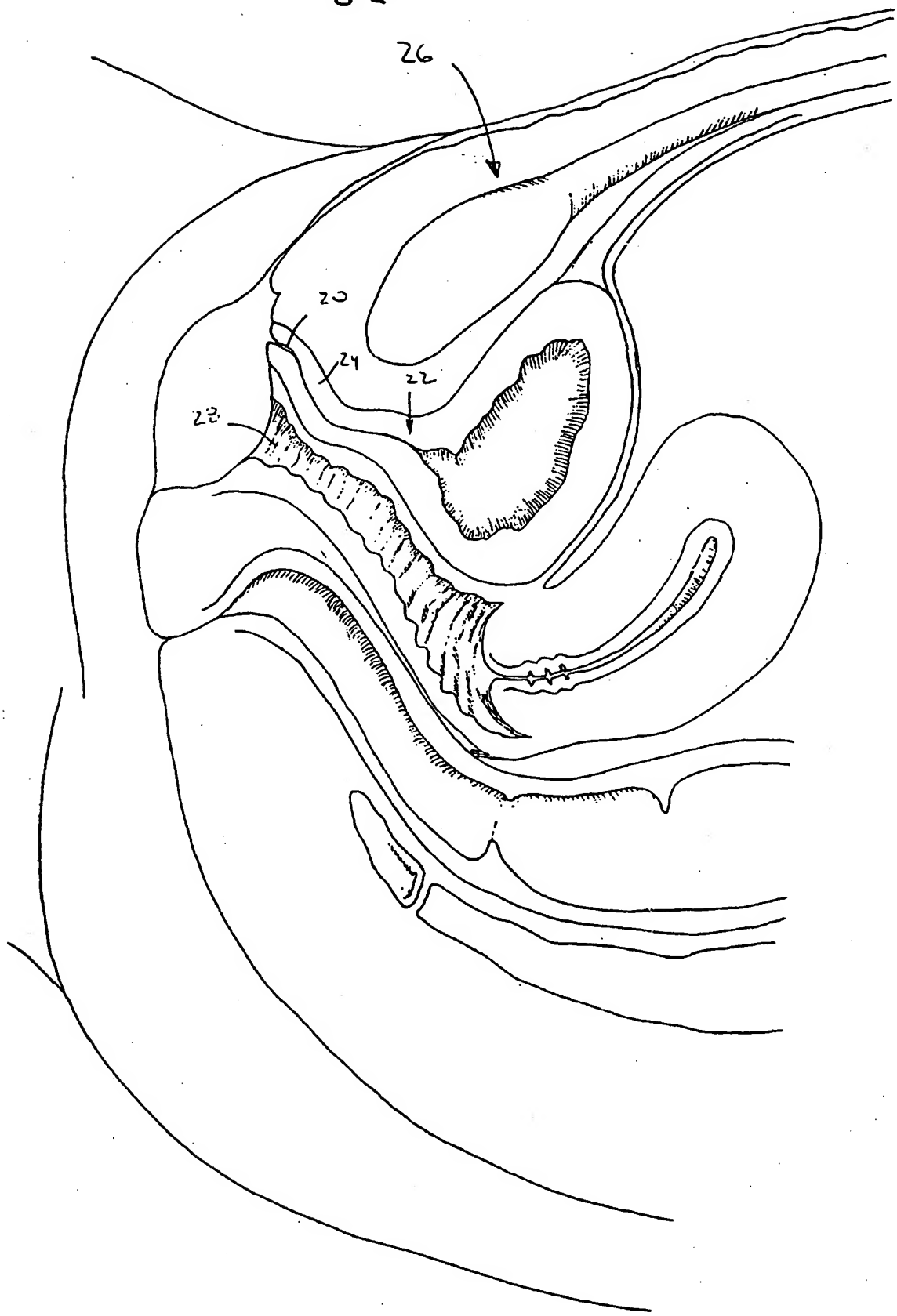
33. The method of claim 32, wherein said projections have a length of greater than about 2 cm when said balloon is fully inflated.

34. The method of claim 29, wherein the width of said slot is about 2.5 cm when said balloon is fully inflated.

35. The method of claim 29, wherein the width of said body is between about 10 and about 14 cm when said balloon is deflated.

36. The method of claim 29, wherein the maximum height of said balloon is between about 5 and about 7 cm when said balloon is fully inflated.

Fig. 1



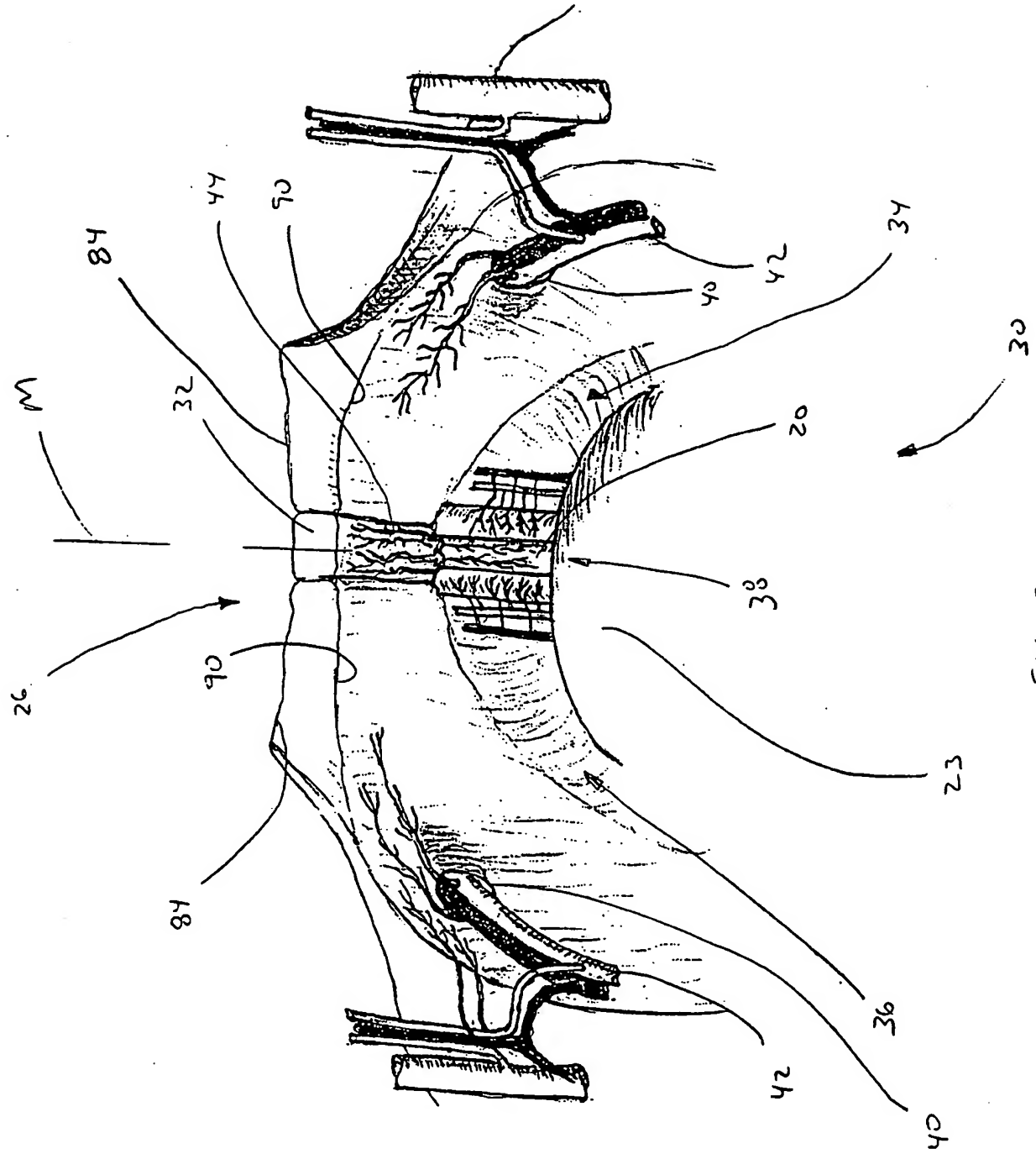


FIG 2

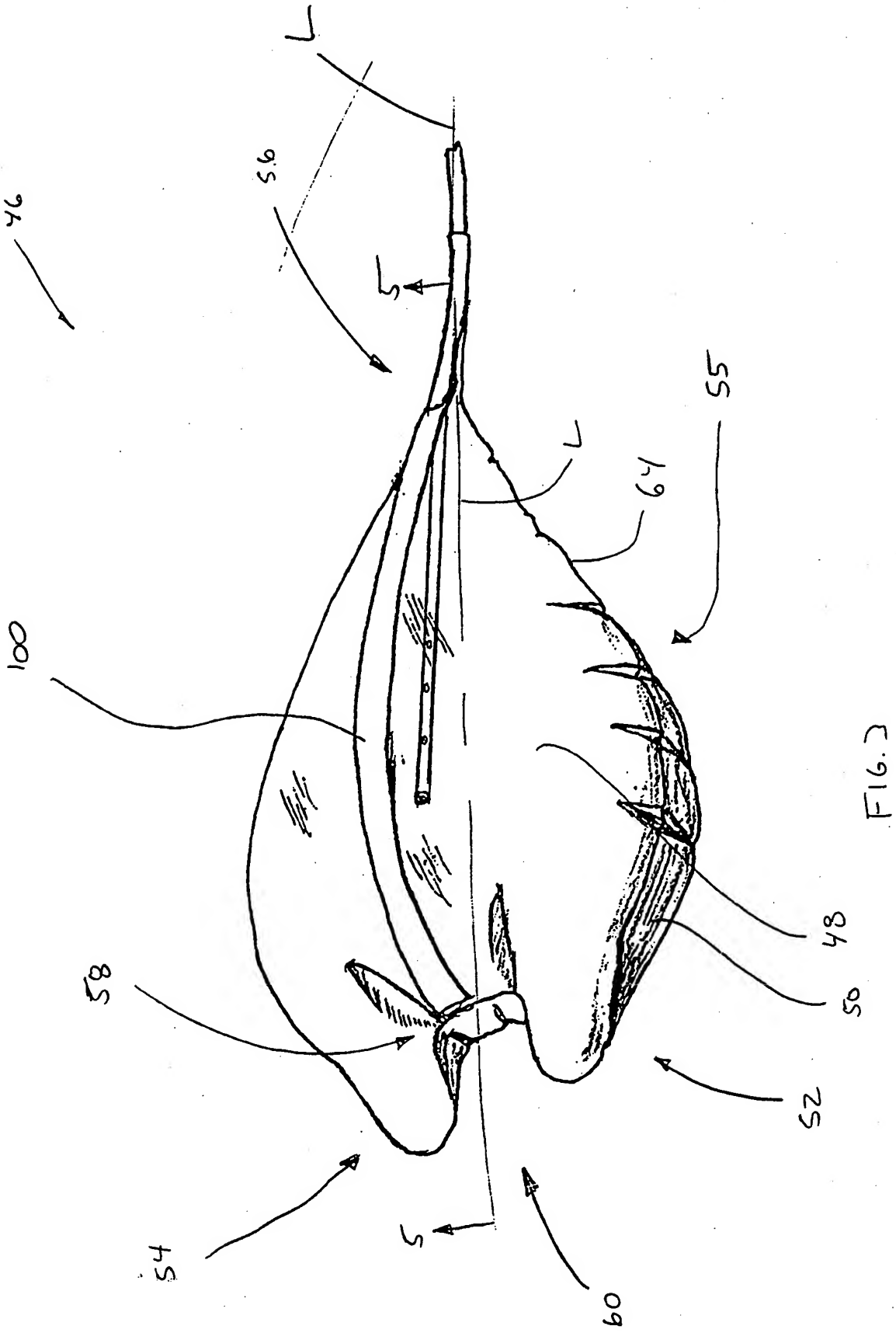


FIG. 3

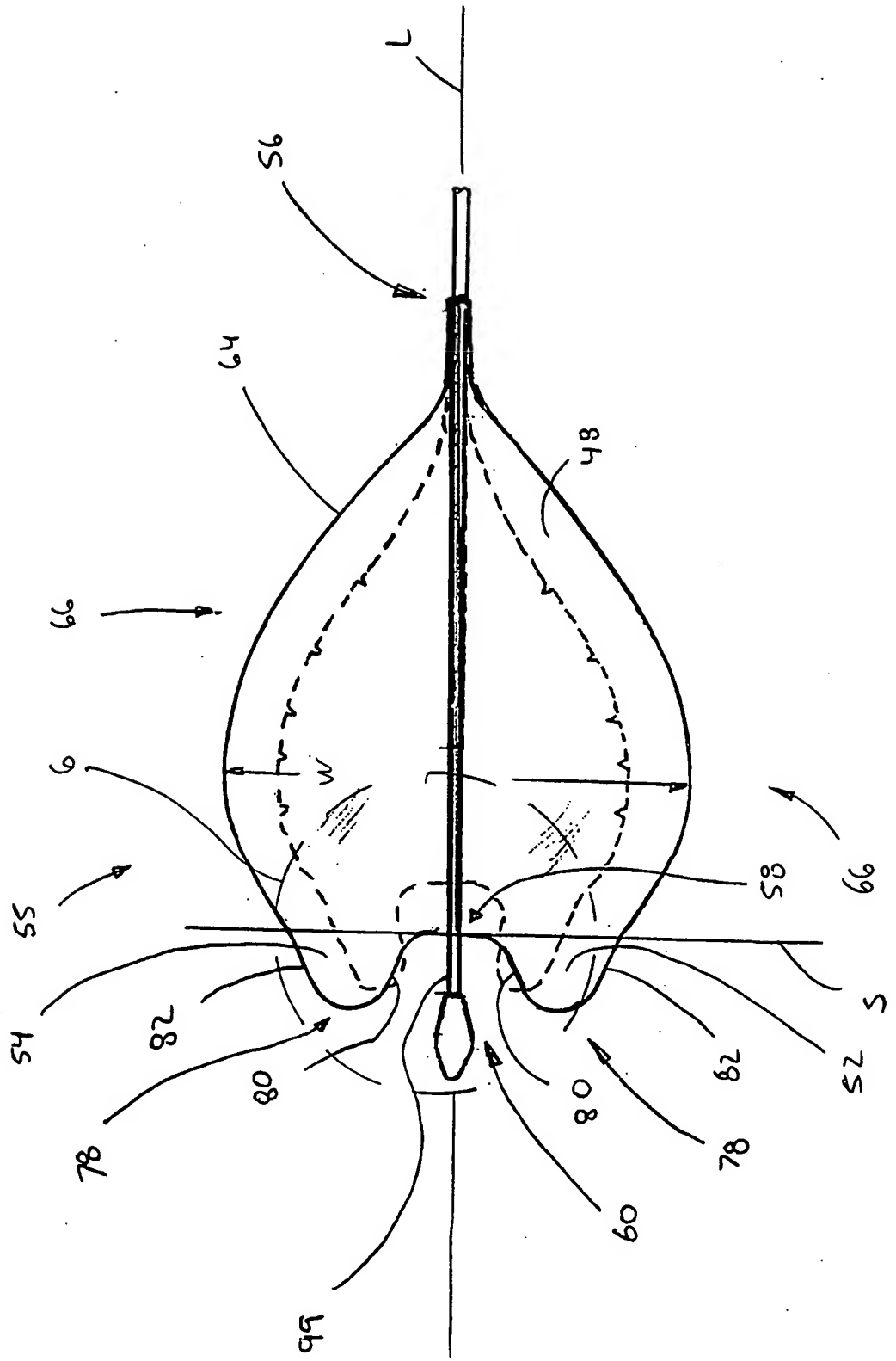


FIG 4

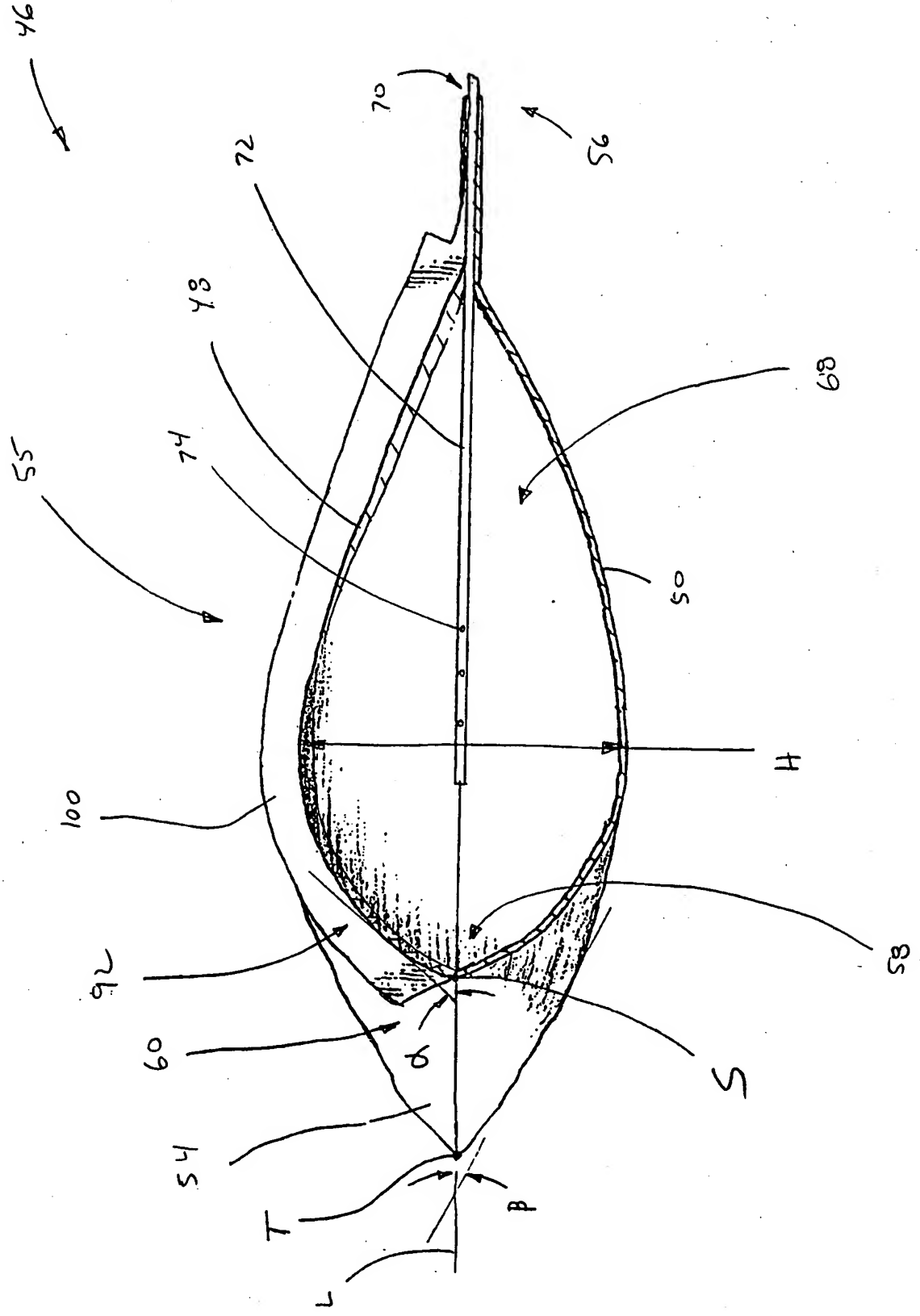
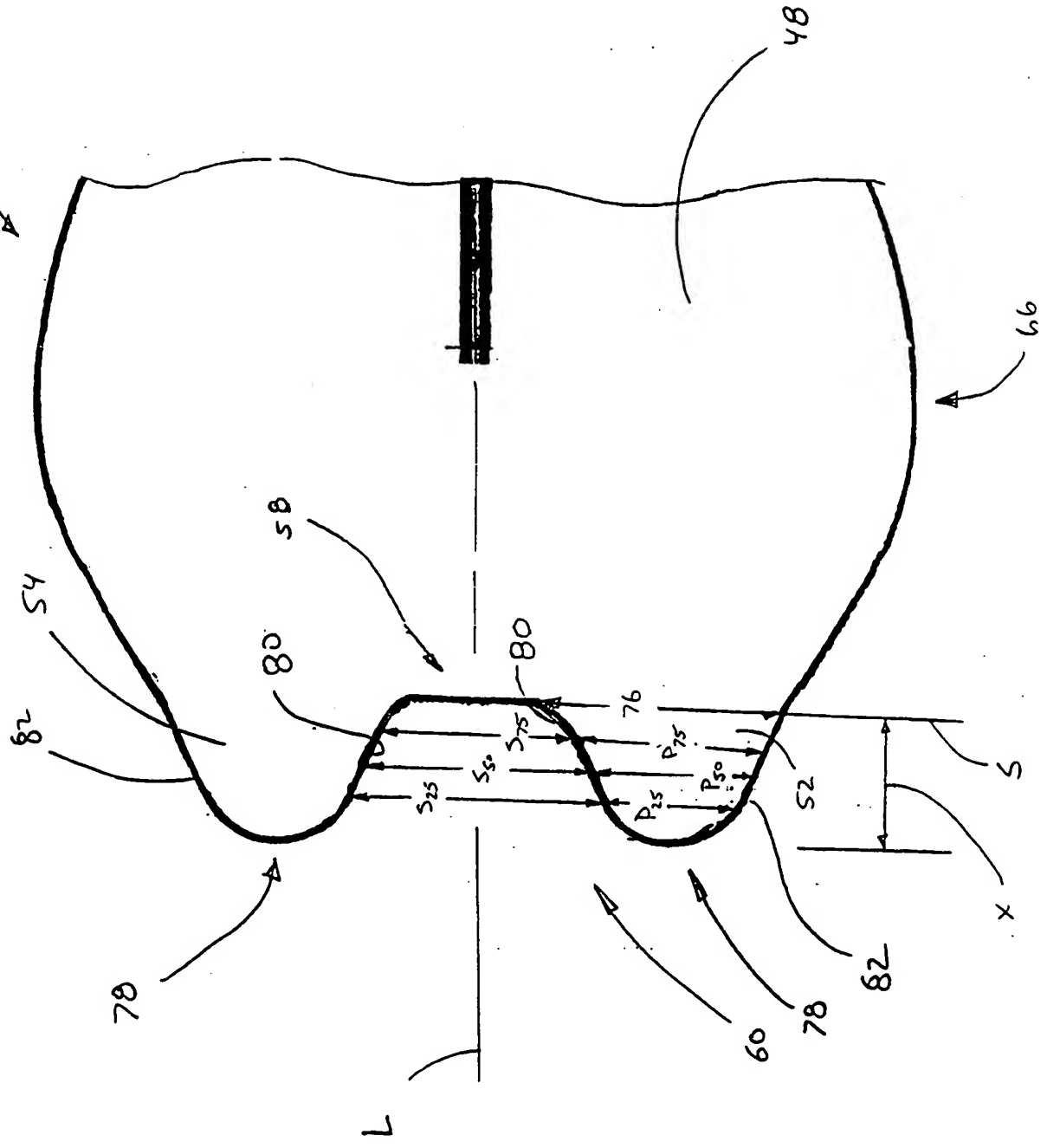


FIG 5

FIG. 6



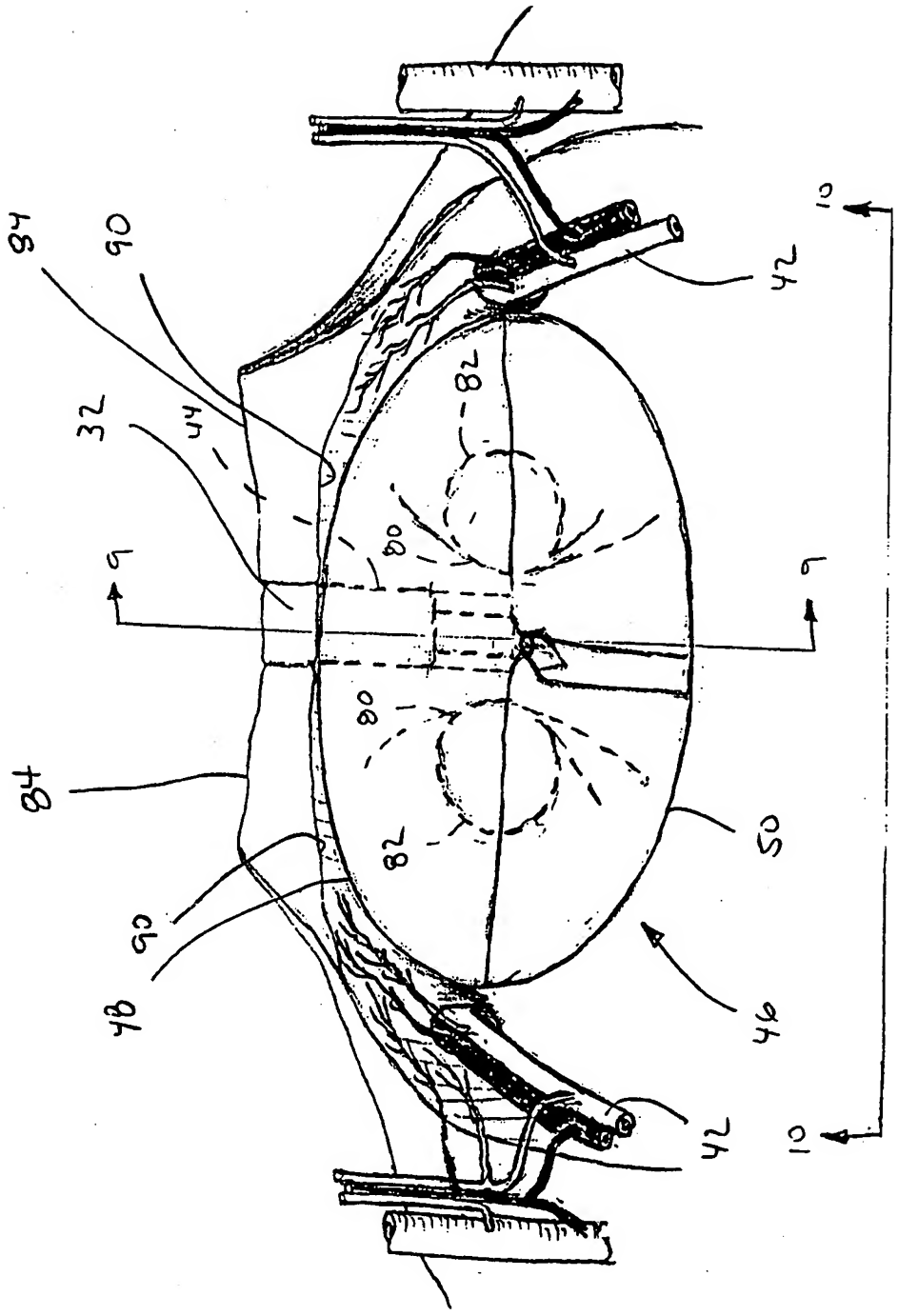


FIG. 7

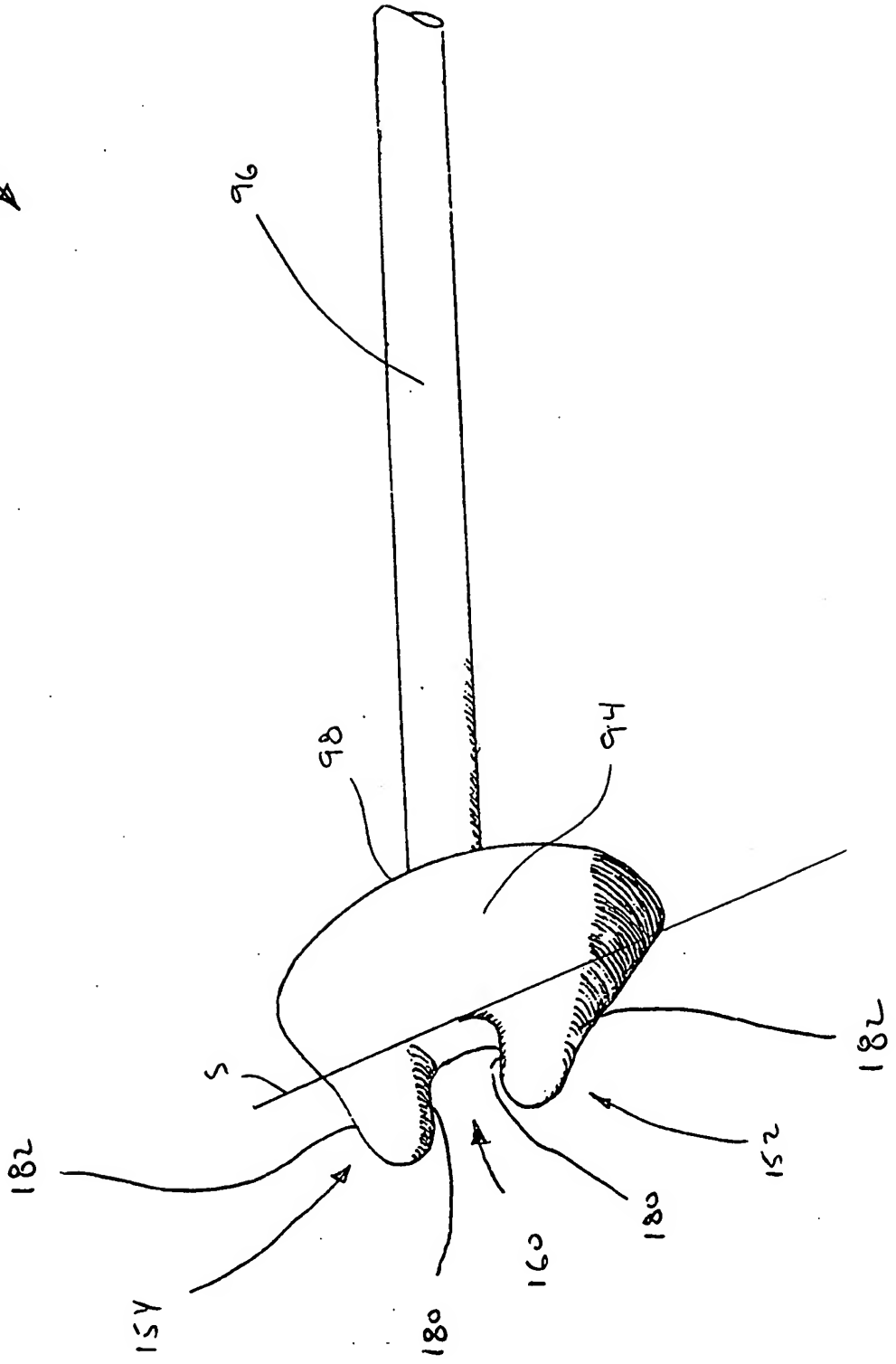


FIG 8

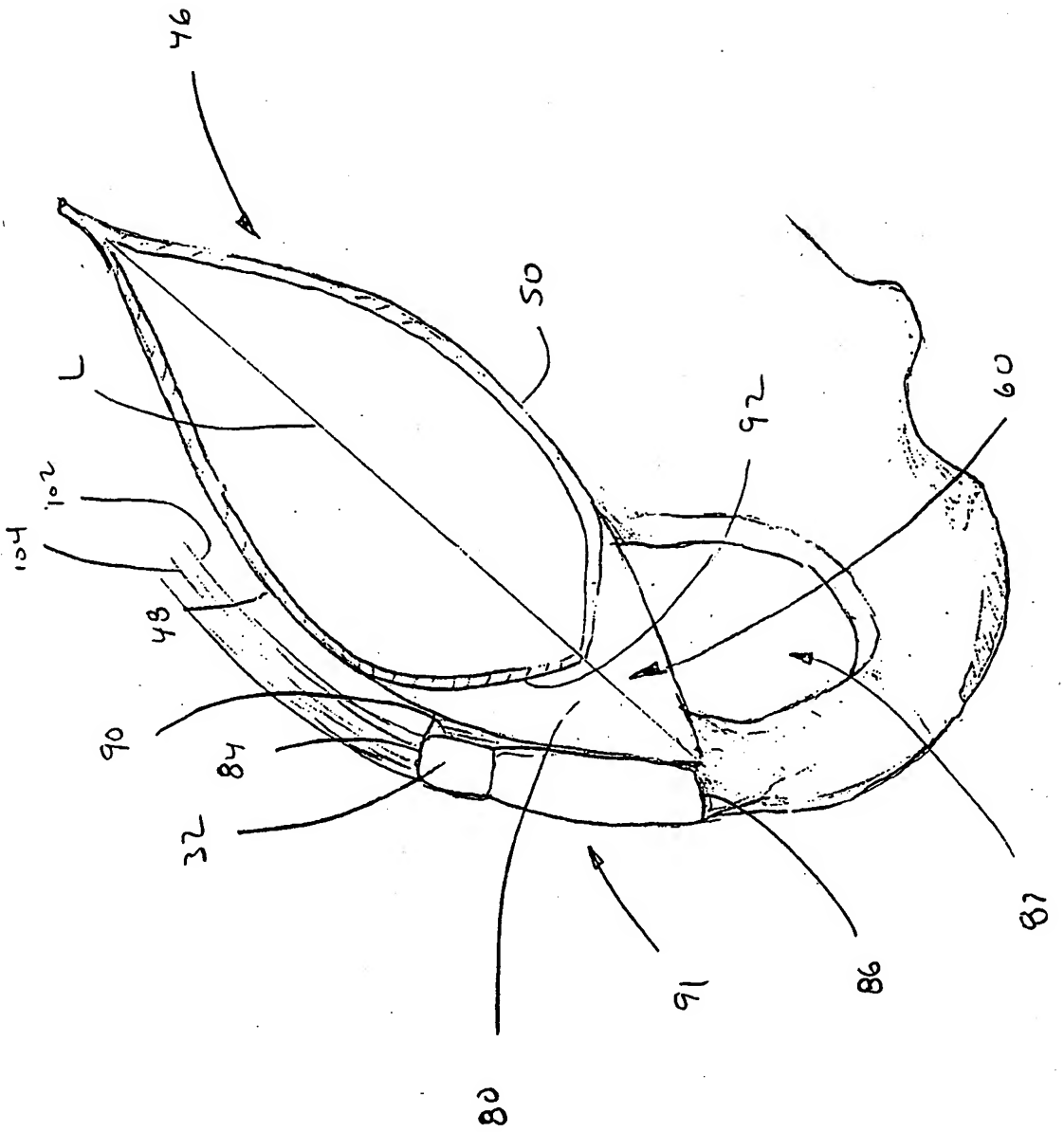


FIG 9

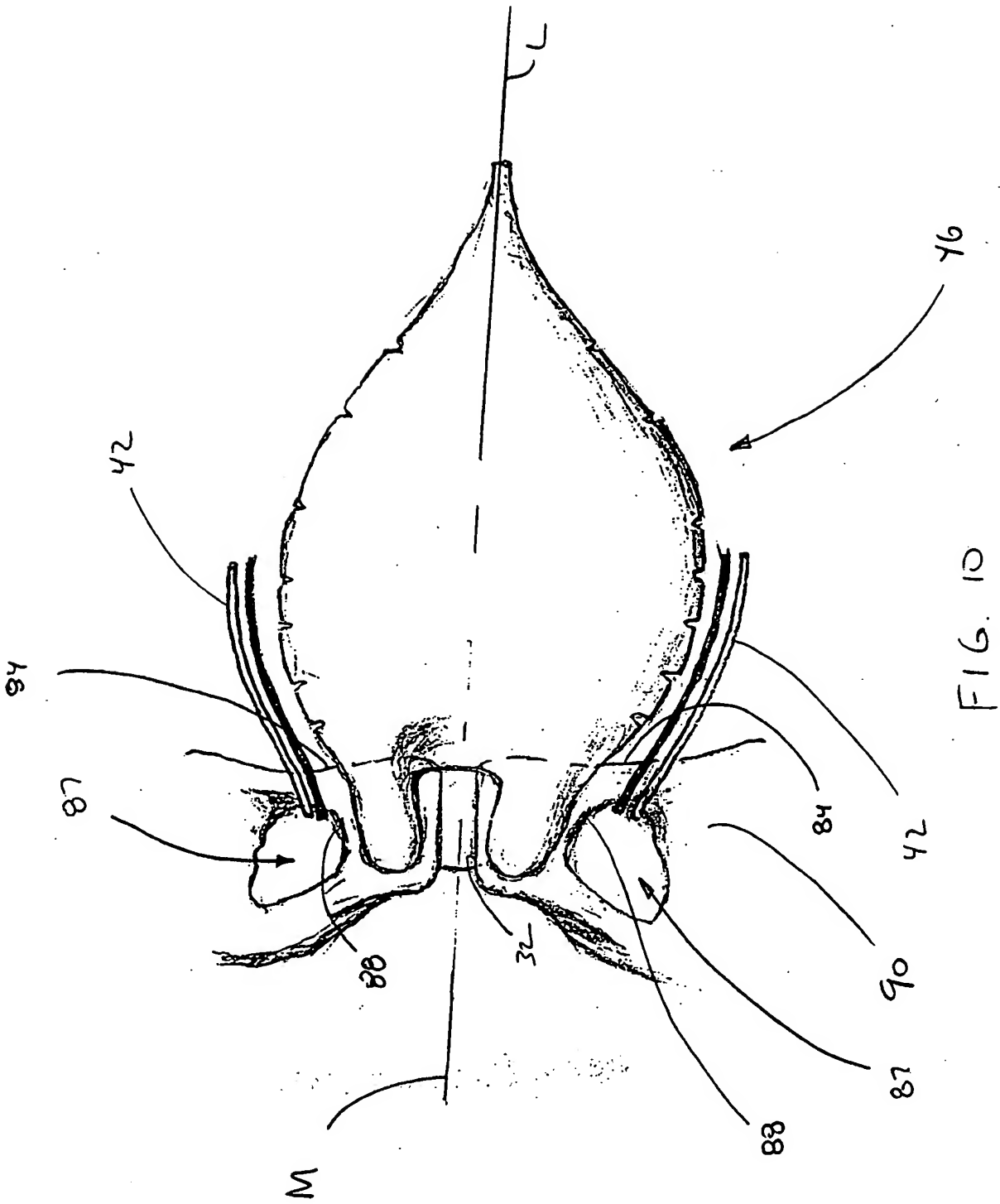


FIG. 10